



0360
4

PATENT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Daniel W. Nebert : Paper No:
Serial No. 09/863,528 : Group Art Unit:
Filed: May 22, 2001 : Examiner:
For: **TRANSGENIC ANIMALS FOR MONITORING WATER QUALITY**

INFORMATION DISCLOSURE STATEMENT

THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. §§1.97 and 1.98, Applicant herewith submits certain patent references and other information, which the Patent & Trademark Office may wish to consider in examining the above-identified application. The references and information are provided below, and are also listed on the attached Form PTO-1449.

<u>PATENTS</u>	<u>INVENTOR</u>	<u>ISSUE DATE</u>
4,736,866	Leder, et al	April 12, 1988
4,800,159	Mullis, et al	January 24, 1989
4,870,009	Evans, et al	September 26, 1989
4,883,750	Whiteley, et al	November 28, 1989
4,965,188	Mullis, et al	October 23, 1990
5,176,995	Sninsky, et al	January 5, 1993
5,378,822	Bradfield, et al	January 3, 1995
5,441,884	Baum	August 15, 1995
5,737,018	Shimizu, et al	April 7, 1998
5,854,010	Denison, et al	December 29, 1998
6,110,693	Barak, et al	August 29, 2000
6,117,639	Germann, et al	September 12, 2000
6,133,027	Yee, et al	October 17, 2000
6,217,847	Contag, et al	April 17, 2001
6,232,107	Bryan, et al	May 15, 2001

OTHER REFERENCES

- Michael J. Carvan III, et al., "Transgenic Zebrafish as Sentinels for Aquatic Pollution," Arch Biochem Biophys 01; 28 pgs.
- Daniel W. Nebert, et al., "Gene-Swap Knock-In Cassette in Mice to Study Allelic Differences in Human Genes," Ann NY Acad Sci 01, 45 pgs.
- Goksoyr, et al., "Application of a Cytochrome P-450 IA1-ELISA in Environmental Monitoring and Toxicological Testing of Fish," Comp. Biochem. Physiol. Vol. 100C, No. 1/2, pp. 157-160 (1991).
- Haasch, et al., "Cloned Rainbow Trout Liver P₁450 Complementary DNA as a Potential Environmental Monitor," Toxicology and Applied Pharmacology 98, 362-368 (1989).
- Rodriguez-Ariza, et al., "Promutagen Activation by Fish Liver as a Biomaarker of Littoral Pollution," Environmental and Molecular Mutagenesis 24:116-123 (1994).
- Powers, "Fish as Model Systems," Science, Vol. 246, (1989).
- Rossant, et al., "Of fin and fur: mutational analysis of vertebrate embryonic development," Genes & Development 6:1-13 (1992).
- Schwab, "Oncogenes and tumor suppressor genes in Xiphophorus," TIG Vol. 3, No. 2 (1987).
- Buchmann, et al., "Immunohistochemical Localization of the Cytochrome P450 Isozymes LMC2 and LM4B (P450IA1) in 2,3,7,8-Tetrachlorodibenzo-p-dioxin-Treated Zebrafish (Brachydanio rerio)," Toxicology and Applied Pharmacology 123, 160-169 (1993).
- Lusska, et al., "Protein-DNA Interactions at a Dioxin-responsive Enhancer," The Journal of Biological Chemistry, V. 268, No. 9, 6575-6580 (1993).
- Heilmann, et al., "Trout P450IA1: cDNA and Deduced Protein Sequence, Expression in Liver, and Evolutionary Significance," DNA, Vol. 7, No. 6 379-387 (1988).
- Rushmore, et al., "The Antioxidant Responsive Element," The Journal of Biological Chemistry Vol. 266, 11632-11639 (1991).
- Jaiswal, "Human NAD(P)H:Quinone Oxidoreductase (NQO₁) Gene Structure and Induction by Dioxin," Biochemistry, 30, 10647-10653 (1991).
- Rushmore, et al. "Regulation of glutathione S-transferase Ya subunit gene expression: Identification of a unique xenobiotic-responsive element controlling inducible expression by planar aromatic compounds," Proc. Natl. Acad. Sci. USA, Vol. 87, 3826-3830 (1990).

- Palmiter, "Regulation of metallothionein genes by heavy metals appears to be mediated by a zinc-sensitive inhibitor that interacts with a constitutively active transcription factor, MTF-1," *Proc. Natl. Acad. Sci. USA*, Vol. 91, 1219-1223 (1994).
- Radtke, et al., "Functional domains of the heavy metal-responsive transcription regulator MTF-1," *Nucleic Acids Research*, Vol. 23, No. 12, 2277-2286 (1995).
- Radtke, et al., "Differential Sensitivity of Zinc Finger Transcription Factors MTF-1, Sp1 and Krox-20 to CpG Methylation of their Binding Sites," *Biol. Chem. Hoppe-Seyler*, Vol. 377, 47-56 (1996).
- Dalton, et al., "Reversible Activation of Mouse Metal Response Element-Binding Transcription Factor 1 DNA Binding Involves Zinc Interaction with the Zinc Finger Domain," *Molecular and Cellular Biology*, 2781-2789 (1997).
- Schmitt, et al., "National Contaminant Biomonitoring Program: Residues of Organochlorine Chemicals in U.S. Freshwater Fish, 1976-1984," *Arch. Environ. Contam. Toxicol.*, 19, 748-781 (1990).
- Payne, et al., "Review and Perspective on the Use of Mixed-Function Oxygenase Enzymes in Biological Monitoring," *Comp. Biochem. Physiol.*, Vol. 86C, No. 2, 233-245 (1987).
- Harnly, et al., "Biological Monitoring for Mercury within a Community with Soil and Fish Contamination," *Environmental Health Perspectives*, Vol. 105, No. 4, 424-429 (1997).
- Tollefson, et al., "Methylmercury in Fish: A Review of Residue Levels, Fish Consumption and Regulatory Action in the United States," *Environmental Health Perspectives*, Vol. 68, 203-208 (1986).
- Talalay, et al., "Chemoprotection against cancer by Phase 2 enzyme induction," *Toxicology Letters*, 82/83, 173-179 (1995).
- Shelby, et al., "Assessing Environmental Chemicals for Estrogenicity Using a Combination of In Vitro and In Vivo Assays," *Environmental Health Perspectives*, Vol. 104, No. 12, 1296-1300 (1996).
- Anolik, et al., "Cooperative Binding of Estrogen Receptor to DNA Depends on Spacing of Binding Sites, Flanking Sequence, and Ligand," *Biochemistry*, 34, 2511-2520 (1995).
- Pakdel, et al., "Full-length sequence and in vitro expression of rainbow trout estrogen receptor cDNA," *Molecular and Cellular Endocrinology*, Vol. 71, 195-204 (1990).
- Goulas, et al., "Isolation and Characterization of a Vitellogenin cDNA from Rainbow Trout (*Oncorhynchus mykiss*) and the Complete Sequence of a Phosvitin Coding Segment," *DNA and Cell Biology*, Vol. 15, No. 7, 605-616 (1996).

Minucci, et al., "*Retinoid X receptor-selective ligands produce malformations in Xenopus embryos*," Proc. Natl. Acad. Sci. USA, Vol. 93, 1803-1807 (1996).

Joore, et al., "*Effects of retinoic acid on the expression of retinoic acid receptors during zebrafish embryogenesis*," Mechanisms of Development, Vol. 46, 137-150 (1994).

Jones, et al., "*New Retinoid X Receptor Subtypes in Zebra Fish (Danio rerio) Differentially Modulate Transcription and Do Not Bind 9-cis Retinoic Acid*," Molecular and Cellular Biology, 5226-5234 (1995).

Chang, et al., "*Axial (HNF3 β) and retinoic acid receptors are regulators of the zebrafish sonic hedgehog promoter*," The EMBO Journal, Vol. 16, No. 13, 3955-3964 (1997).

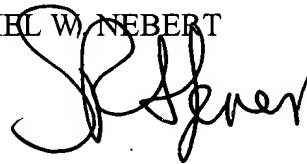
Payne, J.F., "*Field Evaluation of Benzopyrene Hydroxylase Induction as a Monitor for Marine Petroleum Pollution*," Science 191:945-946 (1976).

Copies of the listed references are provided. No representation is made or intended that a prior art search has been made or that no better art than the listed is available. It is respectfully requested that the information be considered by the Examiner and made of record in the present application.

The Assistant Commissioner for Patents is authorized to charge any deficiency or credit any overpayment to Frost Brown Todd LLC Deposit Account No. 06-2226.

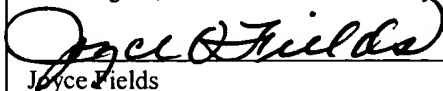
Respectfully submitted,

DANIEL W. NEBERT

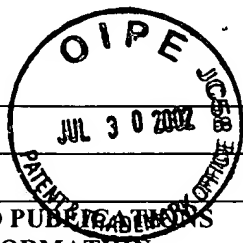


CERTIFICATE OF MAILING

I hereby certify that a copy of this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to The Assistant Commissioner of Patents, Washington, D.C. 20231 this 22nd day of July, 2002.


Joyce Fields

Stephen R. Albainy-Jenei
Registration No. 41,487
Telephone (513) 651-6839
FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202-4182



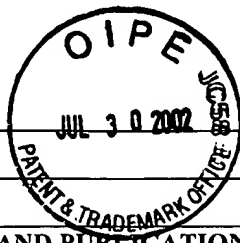
PTO FORM 4/92												
FORM PTO-1449												
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT												
ATTY. DOCKET												
91830/476945												
SERIAL NO.												
09/863,528												
APPLICANT												
Daniel W. Nebert												
FILING DATE												
May 22, 2001												
GROUP												
Exam Init.		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS
		4	7	3	6	8	6	6	April 12, 1988	Leder, et al	800	1
		4	8	0	0	1	5	9	January 24, 1989	Mullis, et al	435	172.3
		4	8	7	0	0	0	9	September 26, 1989	Evans, et al	435	70
		4	8	8	3	7	5	0	November 28, 1989	Whiteley, et al	435	6
		4	9	6	5	1	8	8	October 23, 1990	Mullis, et al	435	6
		5	1	7	6	9	9	5	January 5, 1993	Sninsky, et al	435	6
		5	3	7	8	8	2	2	January 3, 1995	Bradfield, et al	536	23.5
		5	4	4	1	8	8	4	August 15, 1995	Baum	435	252.31
		5	7	3	7	0	1	8	April 7, 1998	Shimizu, et al	348	363
		5	8	5	4	0	1	0	December 29, 1998	Denison, et al	435	8
		6	1	1	0	6	9	3	August 29, 2000	Barak, et al	435	7.2
		6	1	1	7	6	3	9	September 12, 2000	Germann, et al	435	6
		6	1	3	3	0	2	7	October 17, 2000	Yee, et al	435	325
		6	2	1	7	8	4	7	April 17, 2001	Contag, et al	424	9.1
		6	2	3	2	1	0	7	May 15, 2001	Bryan, et al	435	189
FOREIGN PATENT DOCUMENTS												
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS
OTHER ART (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)												
		Michael J. Carvan III, et al., "Transgenic Zebrafish as Sentinels for Aquatic Pollution," Arch Biochem Biophys 01; 28 pgs.										
		Daniel W. Nebert, et al., "Gene-Swap Knock-In Cassette in Mice to Study Allelic Differences in Human Genes," Ann NY Acad Sci 01, 45 pgs.										
		Goksoyr, et al., "Application of a Cytochrome P-450 IA1-ELISA in Environmental Monitoring and Toxicological Testing of Fish," Comp. Biochem. Physiol. Vol. 100C, No. 1/2, pp. 157-160 (1991).										
		REFERENCES CONTINUED ON NEXT PAGES										

EXAMINER_____

DATE CONSIDERED_____

Page 1 of 3

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



PTO FORM 4/92				
FORM PTO-1449	ATTY. DOCKET	91830/476945	SERIAL NO.	09/863,528
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT	Daniel W. Nebert		
	FILING DATE	May 22, 2001	GROUP	

(References continued)

Haasch, et al., "Cloned Rainbow Trout Liver P₁450 Complementary DNA as a Potential Environmental Monitor," Toxicology and Applied Pharmacology 98, 362-368 (1989).

Rodriguez-Ariza, et al., "Promutagen Activation by Fish Liver as a Biomaarker of Littoral Pollution," Environmental and Molecular Mutagenesis 24:116-123 (1994).

Powers, "Fish as Model Systems," Science, Vol. 246, (1989).

Rossant, et al., "Of fin and fur: mutational analysis of vertebrate embryonic development," Genes & Development 6:1-13 (1992).

Schwab, "Oncogenes and tumor suppressor genes in Xiphophorus," TIG Vol. 3, No. 2 (1987).

Buchmann, et al., "Immunohistochemical Localization of the Cytochrome P450 Isozymes LMC2 and LM4B (P450IA1) in 2,3,7,8-Tetrachlorodibenzo-p-dioxin-Treated Zebrafish (Brachydanio rerio)," Toxicology and Applied Pharmacology 123, 160-169 (1993).

Lusska, et al., "Protein-DNA Interactions at a Dioxin-responsive Enhancer," The Journal of Biological Chemistry, V. 268, No. 9, 6575-6580 (1993).

Heilmann, et al., "Trout P450IA1: cDNA and Deduced Protein Sequence, Expression in Liver, and Evolutionary Significance," DNA, Vol. 7, No. 6 379-387 (1988).

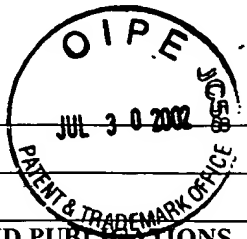
Rushmore, et al., "The Antioxidant Responsive Element," The Journal of Biological Chemistry Vol. 266, 11632-11639 (1991).

Jaiswal, "Human NAD(P)H:Quinone Oxidoreductase (NQO₁) Gene Structure and Induction by Dioxin," Biochemistry, 30, 10647-10653 (1991).

Rushmore, et al. "Regulation of glutathione S-transferase Ya subunit gene expression: Identification of a unique xenobiotic-responsive element controlling inducible expression by planar aromatic compounds," Proc. Natl. Acad. Sci. USA, Vol. 87, 3826-3830 (1990).

Palmiter, "Regulation of metallothionein genes by heavy metals appears to be mediated by a zinc-sensitive inhibitor that interacts with a constitutively active transcription factor, MTF-1," Proc. Natl. Acad. Sci. USA, Vol. 91, 1219-1223 (1994).

Radtke, et al., "Functional domains of the heavy metal-responsive transcription regulator MTF-1," Nucleic Acids Research, Vol. 23, No. 12, 2277-2286 (1995).



PTO FORM 4/92				
FORM PTO-1449	ATTY. DOCKET	91830/476945	SERIAL NO.	09/863,528
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT	Daniel W. Nebert		
	FILING DATE	May 22, 2001	GROUP	

(References continued)

Radtke, et al., "Differential Sensitivity of Zinc Finger Transcription Factors MTF-1, Sp1 and Krox-20 to CpG Methylation of their Binding Sites," Biol. Chem. Hoppe-Seyler, Vol. 377, 47-56 (1996).

Dalton, et al., "Reversible Activation of Mouse Metal Response Element-Binding Transcription Factor 1 DNA Binding Involves Zinc Interaction with the Zinc Finger Domain," Molecular and Cellular Biology, 2781-2789 (1997).

Schmitt, et al., "National Contaminant Biomonitoring Program: Residues of Organochlorine Chemicals in U.S. Freshwater Fish, 1976-1984," Arch. Environ. Contam. Toxicol., 19, 748-781 (1990).

Payne, et al., "Review and Perspective on the Use of Mixed-Function Oxygenase Enzymes in Biological Monitoring," Comp. Biochem. Physiol., Vol. 86C, No. 2, 233-245 (1987).

Harnly, et al., "Biological Monitoring for Mercury within a Community with Soil and Fish Contamination," Environmental Health Perspectives, Vol. 105, No. 4, 424-429 (1997).

Tollefson, et al., "Methylmercury in Fish: A Review of Residue Levels, Fish Consumption and Regulatory Action in the United States," Environmental Health Perspectives, Vol. 68, 203-208 (1986).

Talalay, et al., "Chemoprotection against cancer by Phase 2 enzyme induction," Toxicology Letters, 82/83, 173-179 (1995).

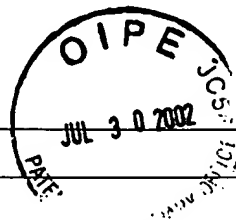
Shelby, et al., "Assessing Environmental Chemicals for Estrogenicity Using a Combination of In Vitro and In Vivo Assays," Environmental Health Perspectives, Vol. 104, No. 12, 1296-1300 (1996).

Anolik, et al., "Cooperative Binding of Estrogen Receptor to DNA Depends on Spacing of Binding Sites, Flanking Sequence, and Ligand," Biochemistry, 34, 2511-2520 (1995).

Pakdel, et al., "Full-length sequence and in vitro expression of rainbow trout estrogen receptor cDNA," Molecular and Cellular Endocrinology, Vol. 71, 195-204 (1990).

Goulas, et al., "Isolation and Characterization of a Vitellogenin cDNA from Rainbow Trout (*Oncorhynchus mykiss*) and the Complete Sequence of a Phosvitin Coding Segment," DNA and Cell Biology, Vol. 15, No. 7, 605-616 (1996).

Minucci, et al., "Retinoid X receptor-selective ligands produce malformations in *Xenopus* embryos," Proc. Natl. Acad. Sci. USA, Vol. 93, 1803-1807 (1996).



PTO FORM 4/92				
FORM PTO-1449	ATTY. DOCKET	91830/476945	SERIAL NO.	09/863,528
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT	Daniel W. Nebert		
	FILING DATE	May 22, 2001	GROUP	

(References continued)

Joore, et al., "Effects of retinoic acid on the expression of retinoic acid receptors during zebrafish embryogenesis," Mechanisms of Development, Vol. 46, 137-150 (1994).

Jones, et al., "New Retinoid X Receptor Subtypes in Zebra Fish (*Danio rerio*) Differentially Modulate Transcription and Do Not Bind 9-cis Retinoic Acid," Molecular and Cellular Biology, 5226-5234 (1995).

Chang, et al., "Axial (*HNF3 β*) and retinoic acid receptors are regulators of the zebrafish sonic hedgehog promoter," The EMBO Journal, Vol. 16, No. 13, 3955-3964 (1997).

Payne, J.F., "Field Evaluation of Benzopyrene Hydroxylase Induction as a Monitor for Marine Petroleum Pollution," Science 191:945-946 (1976).